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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,415	04/03/2007	Norimasa Miura	060387	6081

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	

MAIL DATE	DELIVERY MODE
12/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,415	MIURA ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/22/06, 10/19/06, ~~5/11/07~~*. 9-25-07
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status

1. Claims 1-2 are pending.

Priority

2. This application filed on April 03, 2007 is a 371 of PCT/JP04/17542 filed on 11/18/2004 which claims benefit of foreign application JAPAN 2003-392875 filed on 11/21/2003.

Information Disclosure Statement

3. The information Disclosure Statement filed on May 22, 2006, October 19, 2006 and May 22, 2007 have been considered.

Objection to the abstract of the specification

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because the abstract contains 2 paragraphs and more than 150 words in length. Correction is required. See MPEP § 608.01(b).

Sequence Rules and Objection to the Specification

5. The specification is objected because of the following informalities:

(i) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply the requirements of 37 CFR 1.821 through 1.825. The instant application recites sequences that are not identified by SEQ ID No. (see at least claims 1-2, and page 8) recite a nucleic acid sequence / amino acid sequence with more than 10 nucleotides or 4 amino acids, which is not identified by SEQ ID NO.). Examiner also notes that the application contains no sequence listing either in the form of a paper copy or in a computer readable form. Appropriate correction is required.

Objection to Oath/declaration

6. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the citizenship of the inventor Shiota, Goshi.

Informalities

7. The following informalities are noted:

(i) claim 1-2 recite 'method comprised of;'. 'method comprising:' is suggested.

(ii) Claims 1 and 2 recite 'hTERT' and 'AFP' . Expansion of the abbreviations is suggested.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Kanaya et al. (Int. J. Cancer, Vol. 78, pp. 539-543, 1998).

Note: the instant claims recite sample containing RNA only as a somatic cell and cancer cell fraction, which is interpreted as broadly as comprising tumor and normal tissue cells.

Kanaya et al teach a cancer diagnostic method of claim 1 comprising

a process to obtain the sample containing RNA only as a somatic cell and cancer cell from body fluid (see page 539, col. 2, paragraph 2 under materials and methods section) and a process having a reverse transcription reaction step to generate cDNA using reverse transcriptase from the sample containing said RNA only (see page 540, col.1, paragraph under RT-PCR section) and a PCR step utilizing fluorescent dye (SYBR green I) using the primers for hTERT, CGGAAGAGTGTCTGGAGCAA , and GGATGAAGCGGAGTCTGGA to quantify said PCR product amplified by PCR reaction using the fluorescent dye binding to the PCR product (see page 540, col. 1, paragraph under RT-PCR section). Accordingly Kanaya et al. anticipates the instant claim.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Witzigmann et al. (Surgery, Vol. 131, pp. 34-43, 2002) in view of Lowe et al. (Nucleic Acids Research, Vol. 18, No. 7, page 1757-1761, 1990).

Witzigmann et al. teach a cancer diagnostic method of claim 2 comprising

a process to obtain the sample containing RNA only as a somatic cell and cancer cell from body fluid and a process having a reverse transcription reaction step to generate cDNA using reverse transcriptase from the sample containing said RNA only and a PCR step utilizing fluorescent dye using the primers for AFP, to quantify said PCR product amplified by PCR reaction using the fluorescent dye binding to the PCR product (see 35, col. 2, paragraph 1 under blood samples sub-title, paragraphs 1-3 under AFP mRNA assay sub-title, page 36, col. 1, line 1-12, paragraphs 1-3).

However Witzigmann et al. did not specifically teach AFP primers as claimed in claim 2.

Lowe et al. teach a method for designing primers and evaluating their performance wherein Lowe et al. disclose a computer program for rapid selection of oligonucleotide primers for polymerase chain reaction (see page 1757, col. 1, abstract). Lowe et al. teach that all primers designed for over 10 gene products were experimentally tested and the results shoed that all the amplification products specified by the primers are of the predicted size and also hybridize with the appropriate cDNA or internal oligonucleotide probe (see page 1760, col. 2, paragraph 1).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine the method of detecting AFP mRNA as taught by Witzigmann et al. with a step of designing and generating primers from known sequences as taught by Lowe et al. to develop a sensitive and improved detection method because it is well known (as taught by Witzigmann et al.) to an ordinary skill in the art at the time the invention was made, to generate primers from the known sequences as taught by Witzigmann et al. Further it is also known (as taught by Lowe et al.) to design specific primers using computer program based on known sequences. The ordinary artisan would have had a reasonable expectation of success that such primers generated using known sequences as taught by Witzimann et al. in view of Lowe et al. for AFP detection because the claimed primers are functional equivalents of the sequences taught by Witzigmann et al. and Lowe et al. further supported the specificity of custom designed primers. The ordinary artisan would have been motivated to generate a number of said primers and primer pairs for detection of AFP, such primers and primer pairs are considered functionally equivalent to the claimed primers and primer pairs in the absence of secondary considerations. Further, selection of specific oligonucleotides for specific Tm represents routine optimization with regard to sequence, length and composition of the oligonucleotide, which routine optimization parameters are explicitly recognized in Lowe et al. (This clearly shows that every primer would have a reasonable expectation of success). As noted in *In re Aller*, 105 USPQ 233

at 235, more particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the probe or primer selection performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Primary Examiner,

Prabha Chunduru
SURYAPRABHA CHUNDURU 12/10/07
PRIMARY EXAMINER